MAR - 5 2010

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San Jose, CA 95138
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K093677

stryker®
Endoscopy

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Device Name

Proprietary Name:	Stryker Arthroscope
Common and Usual Names:	Stryker Arthroscope
Classification Name:	Arthroscope (21 CFR § 888.1100, Product Code HRX)

Intended Use: Stryker Arthroscopes are endoscopic devices introduced into a patient to provide an internal view or image of the interior of a joint for examination, diagnosis, and/or therapy. Arthroscopes are indicated for use in arthroscopic procedures performed in the hip, knee, shoulder, wrist (carpel tunnel syndrome), temporal mandibular joint, ankle, elbow, and feet (plantar fascia release).

Device Description: Stryker Arthroscopes are endoscopic devices introduced into a patient to provide an internal view or image of the interior of a joint for examination, diagnosis, and/or therapy. The Stryker Arthroscope is a long tube containing a series of lenses. At the distal end, an objective lens captures the image of the object. Lens along the rod relay the image. At the proximal end, a proximal coupling lens relays the image to a CCD (Camera).

The Stryker Arthroscopes come in various diameters including 1.9mm, 2.3mm, 2.7mm, and 4.0mm. Larger size arthroscopes are used for general viewing, while smaller diameter arthroscopes are used for restricted surgical sites. The Stryker Arthroscopes come in several directions of view including, 0°, 30°,45°, 70°. The direction of view enables viewing of different parts. Materials of the Arthroscope include stainless steel, titanium, PEEK, Glass, and Sapphire.

Technological Characteristics: The Stryker Arthroscopes are substantially equivalent in construction and materials to the predicate Henke Sass Wolf Arthroscopes (K080560).

	Proposed Device	**Predicate Device**	**Equivalence**	**Impact on Safety and Effectiveness**
Device	Stryker Arthroscope	HSW Arthroscope		
Technological Characteristics (Design)				
Field of View (FOV), Degrees	105°, 80°, 65°	85°, 105°	Different	The differences in the Field of view do not affect the safety and efficacy of the device.
Direction of View	0°, 30°, 45°, 70°	0°, 30°, 45°, 70°, 110°	Same	N/A

Outer Diameter	4mmm, 2.7mm, 2.3mm, 1.9mm	4mm, 2.3mm-2.9mm, 1.7-1.9mm	Same	N/A
Working Length	165mm, 140mm, 120mm, 75mm, 72mm, 58mm	195mm, 185mm, 140mm, 70mm, 60mm	Different	The lengths are within the range of the predicate. The differences in the length do not affect the safety and efficacy of the device.
Single Use or Reusable	Reusable	Reusable	Same	Equivalent
Light Guide End Adapter	Storz and Olympus	ACMI, Storz, Olympus, Wolf & Dyonics	Same	N/A

Voluntary Safety and Performance Standards: The Stryker Arthroscopes conform to the voluntary standards including but not limited to (Refer to **Section 5.1**):

Biological Evaluation of Medical Devices

10993-1: Biological Evaluation of Medical Devices-Part 1: Evaluation and Testing

10993-10: Biological Evaluation of Medical Devices - Part 10: Tests for Irritation and Delayed-Type Hypersensitivity

Electrical Safety Requirements Per 60601

IEC 60601-1: Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance

IEC 60601-2-18: Medical Electrical Equipment - Part 2: Particular Requirements for the safety of endoscopic equipment

AAMI/ISO Standards for Sterilization of Medical Devices

TIR 12: Designing, Testing and Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities

ISO 14937: Sterilization of Health Care Products - General Requirements for Characterization of a Sterilizing Agent and the Development, Validation, and Routine Control of a Sterilization Process for Medical Devices

Optics

ISO 8600-1: Optics and photonics — Medical endoscopes and endotherapy devices — Part 1: General requirements

ISO 8600-3: Optics and optical instruments: Medical endoscopes and endoscopic accessories Part 3: Determination of field of view and direction of view of endoscopes with optics

ISO 8600-5: Optics and photonics-Medical Endoscopes and Endoscopic Accessories-Part 5: Determination of Optical Resolution of rigid endoscopes with optics.

Performance Testing: The subject device has been subjected to and passed electrical safety, sterilization, and biocompatibility testing requirements. The patient contacting materials are identical to the materials used in the predicated device (Henke Sass Wolf Arthroscope K080560). The Stryker Arthroscopes met all specified design and performance requirements.

Predicate Devices: The Stryker Arthroscopes are substantially equivalent in terms of safety and effectiveness to the currently marketed device, Henke Sass Wolf Arthroscopes (K080560).

Substantial Equivalence: The technological differences between the Stryker Arthroscope and Henke Sass Wolf Arthroscopes do not raise new questions of safety or effectiveness. Therefore the Stryker Arthroscopes are substantially equivalent to the previously cleared Henke Sass Wolf Arthroscope (K080560). Refer to Section 7.0 for a detailed comparison.

Contact:

Feb 25, 2010

Shibir Desai
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Email: Shibir.Desai@stryker.com

Date:

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

MAR - 5 2010

Stryker Endoscopy
% Shibir Desai
Regulatory Affairs Analyst
5900 Optical Court
San Jose, California 95136

Re: K093677
Trade/Device Name: Stryker Arthroscope
Regulation Number: 21 CFR 888.1100
Regulation Name: Arthroscope
Regulatory Class: II
Product Code: HRX
Dated: February 25, 2010
Received: March 2, 2010

Dear Shibir Desai:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

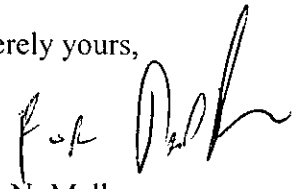
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INTENDED USE

Device Name: Stryker Arthroscope

510(k) Number if known: K093677

Stryker **Arthroscopes** are endoscopic devices introduced into a patient to provide an internal view or image of the interior of a joint for examination, diagnosis, and/or therapy. Arthroscopes are indicated for use in arthroscopic procedures performed in the hip, knee, shoulder, wrist (carpel tunnel syndrome), temporal mandibular joint, ankle, elbow, and feet (plantar fascia release).

No known contraindications.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use (21 CFR 801 Subpart C) _____

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K093677